REMARKS

Claims 34 to 38 remain in the application and stand rejected. Applicants are grateful to the Examiner for the telephone interview of July 28, 2010, wherein claim 34 and references Sisley and Cianci (U.S. Patent No. 4,149,539) were discussed although no agreement was reached. Applicants also note appreciably that the Examiner has withdrawn references Raulerson and Bierman et al as being bases for grounds of rejection.

Claim 34 and the Specification at paragraph [0054] are amended to remove the "new matter" identified in the Office Action, comprising the phrase "a plurality of potential sites." Paragraph [0057] is also amended to provide express support for a new limitation of claim 34.

Claim 34 is further amended to distinguish over the prior art, to include that: 1) the hub is releasably attached to the catheter by the practitioner at a site selected by the practitioner along coextending lengths of the first and second proximal end regions; 2) the site is spaced from the proximal ends of the first and second proximal end regions; 3) the first and second proximal end regions extend proximally beyond the proximal hub end and spaced apart from each other; and 4) other portions of the proximal end regions of the first and second catheters extend distally from the hub member separately from but adjacent to each other. Support for these amendments is found in Figures 11 and 12, with express support now provided in paragraphs [0054] and [0057].

Claims 34 and 35 stand rejected under 35 USC 103(a) as being unpatentable over Sisley et al (U.S. Patent No. 4,405,313) in view of Bierman (U.S. Patent No. 6,361,523) or Cianci (U.S. Patent No. 4,149,539). Claims 34 and 35 stand alternatively rejected under 35 USC 103(a) as being unpatentable over Hobbs et al (U.S. Patent No. 7,347,852) in view of Bierman.

Claims 36 and 37 stand rejected under 35 USC 103(a) as being unpatentable over Sisley et al in view of Bierman or Cianci and further in view of Ash et al (U.S. Patent No. 5,947,953). Alternatively, claims 36 and 37 stand rejected under 35 USC 103(a) as being unpatentable over Hobbs et al in view of Bierman and further in view of Ash et al (U.S. Patent No. 5,947,953).

Claim 38 stands rejected under 35 USC 103(a) as being unpatentable over Sisley et al in view of Bierman and Ash et al in view of Cazal (U.S. Patent No. 5,800,414). Alternatively, claim 38 stands rejected under 35 USC 103(a) as being unpatentable over Hobbs et al in view of Bierman and Ash et al in view of Cazal (U.S. Patent No. 5,800,414).

Claims 34 to 38 also stand provisionally rejected under "nonstatutory obviousness-type double patenting" in view of Serial No. 10/974,267.

References Sisley et al, Ash et al and Cazal have been discussed and distinguished in previous responses.

Reference Bierman (U.S. Patent No. 6,361,523) sets forth a retainer 20 having an adhesive base 12 affixable to a patient to secure a Foley catheter 8 used to catheterize the patient's bladder for voiding, with the retainer being a clamp releasably securable about the Y-site 112 of the catheter outside the patient such that the catheter is anchored against especially axial movement after patient placement. The Y-site of the Foley catheter is that location where an inflation branch 114 diverges from the drainage branch 116 (Fig. 6). The retainer includes post portions 74,78 (Fig. 5a) to extend vertically between the branches just as they exit the retainer extending in a direction away from the patient, while the main catheter body 118 extends as a unified structure from the retainer toward the patient. The Y-site 112 is at a fixed location along the catheter, and the retainer must be placed at that fixed location.

Reference Cianci sets forth a balloon catheter for use in urology to assist in control of bleeding following a prostatectomy, wherein an inflation lumen extends to the inflatable balloon adjacent the distal catheter end (i.e., the end toward the patient), wherein the catheter is inserted through the urethra and into the bladder until the balloon is distally of the prostate site. The catheter has at least two lumens and includes an angled proximal portion 34 containing one lumen (see Fig. 3), and is to be disposed outside the patient. Prior to catheter insertion into the patient, the catheter is removably inserted through a one-piece traction member comprising a retaining member having a side port projecting proximally at an angle therefrom to accommodate the angled catheter portion. The traction member is needed outside the body to assure that the balloon presses against the prostate site until bleeding stops following the prostatectomy. The retaining member defines a single distal end channel for the catheter 16 to extend distally therefrom, and a pair of proximal channels 42,44 along which are disposed the main catheter portion 32 and the angled catheter portion, and a slot 48 joins the two channels and is open to the proximal retaining member end to permit catheter insertion from proximally of the retaining member, as best shown in Figure 8.

The hub of the present invention is attachable to the catheter by the practitioner at a site selected by the practitioner along lengths of the first and second proximal catheter portions. Within the hub, the catheter portions will be disposed in respective channels. Portions of the first and second catheters coextend separately but adjacently in a direction distally from the single distal

exit of the hub, while other portions thereof extend separately and spaced apart from each other extending proximally from respective exits of the hub.

Regarding the rejection of amended claim 34 based on Sisley et al in view of Bierman, the Office Action asserts that the hub member/splitter 22 of Sisley can be replaced with a releasably attachable hub member as in, for example, Bierman. The "splitter 22" of Sisley is understood to be affixed at the factory, with no suggestion of action related thereto on the part of the practitioner. There is no line of reasoning provided as to why the artisan of routine skill would consider substituting a releasably securable "hub" as in Bierman, since the catheter assembly of Sisley is manufactured to be ready for use by the practitioner, with proximal end fittings already affixed to the catheter, and to be efficiently implanted into a patient in as little time as possible, with minimal steps to be performed by the practitioner. There is no disclosure or suggestion in Sisley of any variable length to the catheter proximal ends to be obtained by the practioner at the patient's bedside, or desire to repair an already implanted catheter assembly. Further, the catheter assembly of Sisley has filled-in portions 16,18 that must be protected against the possibility of being split, as expressly provided at column 5, lines 31 to 35. The Office Action fails to explain an advantage that the artisan would expect successfully to obtain from a releasable hub. Further, in Bierman, the practioner is not presented with situations where the ability to select a location along lengths of two separate catheter portions would be any advantage. It is clear that the combination is prompted by impermissible hindsight after the Examiner has had the benefit of reading the present application. Applicants respectfully traverse the combination and the rejection.

Regarding the rejection of claim 34 based on Sisley et al in view of Cianci, the same arguments and traversals apply as with Sisley et al in view of Bierman, above.

The Office Action continues to cite *In re Hutchison*, as support for holding that the phrase in claim 34 "adapted to be releasably attachable by a practitioner" carries no patentable weight. Applicants propound that the case does not hold that such a phrase never carries patentable weight, since *In re Venezia* holds contrarily. The limitation in claim 34 is used to, among other things, economically provide that the hub is not affixed to the catheter when received by the practioner at the patient's bedside for patient implantation (i.e., being separate is structural), is easily affixable to the catheter by the practitioner (being manipulated and including a locking or clamping arrangement is structural), and to enable the practioner thereafter to remove the hub easily from the catheter for adjustment or repair of the catheter and be re-affixed (having re-usable manipulatable

structures enabling hub opening and re-closing, those structures not requiring being destroyed to be removed from the catheter); all thereof are structural in nature. Further, details of any one of these aspects would be unnecessarily involved and unnecessarily limiting in an independent claim, which is the primary reason that "adapted to" phraseology is accepted as being structural, and therefore a true limitation to be given full patentable weight. It clearly is a distinction over Sisley et al, and Applicants may rely thereon in distinguishing over the prior art.

Claim 35 depends from claim 34, which is believed to patentably distinguish over the reference, and therefore, claim 35 is believed patentable.

Reference Hobbs et al sets forth a catheter assembly implantable into a patient such as for hemodialysis, and that is adapted to not require subcutaneous tunneling for anchoring against axial movement, and to be easily removed from the patient at a later date with minimal or no surgical treatment involved. The catheter comprises two separate catheters whose sidewalls are joined to each other, not by a hub, but in a manner akin to sewing or stapling them to each other along an attachment zone 14 (see Fig. 2), at a site spaced proximally from the distal catheter ends a sufficient distance as to be outside the blood vessel into which the distal portions of the catheters extend. Just proximally of the zone is a separating prong 16 assuring diverging of the proximal catheter portions. The attachment zone and related prong are subcutaneously implanted for anchoring benefits, along with substantial lengths of the two diverging proximal catheter portions (see Fig. 1). At least one thread or wire used in sewing the catheters to each other in the zone, extends to a proximal end accessible by the practitioner outside the patient, to be pulled proximally by the practitioner, thereby detaching itself from the catheter sidewalls, whereafter the catheters are independent from each other and may be easily removed. The attachment of the catheters to each other is performed at the factory, not by the practitioner.

With respect to the rejection of amended claim 34 over Hobbs et al in view of Bierman or Cianci, the catheter assembly of Hobbs et al is disclosed expressly to have an attachment zone that is in lieu of a hub and that is not along the proximal end regions of the two catheters, but instead is near the distal end portions and is implanted into the patient and therefore is not exposed to the practitioner. The Office Action asserts that it would have been obvious to the skilled artisan "to modify the device of Hobbs with a hub assembly, as taught by Bierman." However, again, the Office Action fails to explain an advantage that the artisan would expect successfully to obtain from a releasable hub. This is especially so in that Hobbs et al expressly teaches away from a hub

at all, yet alone a releasably attachable hub; in Hobbs et al, the attachment zone is not accessible after implantation for repairing the catheter assembly while implanted, and the attachment is expressly taught to be performed at the factory, not by the practitioner. Further, in both Hobbs et al and Bierman, the practioner is not presented with situations where the ability to select a location along lengths of two separate catheter portions would be any advantage. It is clear that the combination is prompted by impermissible hindsight after the Examiner has had the benefit of reading the present application. Applicants respectfully traverse the combination and the rejection.

Regarding the rejection of claim 34 based on Hobbs et al in view of Cianci, the same arguments and traversals apply as with Hobbs et al in view of Bierman, above.

Claim 35 depends from claim 34, which is believed to patentably distinguish over the reference, and therefore, claim 35 is believed patentable.

With respect to the rejection of claims 36 and 37 based on Sisley et al in view of Bierman/Cianci further in view of Ash, or alternatively, based on Hobbs et al in view of Bierman/Cianci further in view of Ash, claims 36 and 37 depend from claim 34 and therefore are believed to be themselves patentable.

Regarding the rejections of claim 38 based inter alia on Cazal, the Office Action asserts, since Cazal discloses adhesive being used to join first and second catheters to each other, that "[it] is noted that the adhesive 14 or 20 is capable of being splitted if using sufficient force to tear it." However, there is a limit to what constitutes "sufficient force" that is understood by the artisan of routine skill, that being a level reasonably expected to be appliable by the practitioner in order to intentionally split apart the two catheters without damaging them, should the practitioner desire to split them. The artisan would also consider the entire disclosure of Cazal, including the express teaching that adhesive 14 or 20 is applied (implicitly, by the practitioner) after all desired splitting and has properties sufficient to prevent further splitting, since in the reference any such further splitting is undesired (see column 2, lines 39 to 44). Applicants respectfully traverse the assertion and the rejection.

Claims 34 to 38 stand rejected for "nonstatutory obviousness-type double patenting" in view of the claims of pending but later-filed continuation-in-part application Serial No. 10/974,267. The present rejection is only provisional, since the present application has a filing date earlier than the other application and once all other rejections of the present claims is overcome, the double patenting is required to be withdrawn and the present application issue.

Applicants traverse the assertion in the Office Action that the claims of the other application which do not include a hub limitation, cover the present claims of a hub adapted to be releasably attachable to portions of catheter lumens distal of their proximal ends.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new limitations have been entered into the claims, and no new issues are raised. No new matter has been entered hereby. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

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